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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,304	07/11/2005	Ian Revie	1781-0010	6005

7590 06/20/2006

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EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/505,304

Applicant(s)

REVIE ET AL.

Examiner

Matthew J. Kasztejna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on March 27, 2006, amended claims 2-3, 5-10; new claims 11-18 and canceled claim 1 are acknowledged. The current rejections of claims *stand*. The previous indication of allowability of claims 5 and 8 is *withdrawn* upon further review. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 5-6, 8-12, 15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (U.S. Patent No. 6,272,370).

In regard to claims 2, 5, 8-12 and 17-18, Gillies et al. teach a microcatheter 1 comprised of an elongate shaft with a plurality of MR-visible markers 6 disposed at the distal end to provide easily identifiable reference points for trackability and localization under MR imaging and X-ray fluoroscopy (see Figure 1 and col. 25, lines 39-43). The markers 6 can be formed of radioopaque materials, such as gold, platinum or tantalum, which are more reflective than the copolymer of the shaft 2 of the microcatheter 1 (see col. 25, lines 10-53). Inherent in the disclosure of the use of an MR or x-ray imaging device is the use of at least two receiving devices spaced apart for receiving stereoscopic signals from the markers 6 and a data processor for analyzing the signal

from the markers 6 and generating information relating to the position and orientation of the microcatheter 1. Gillies et al. disclose the movement of the tip can be actuated by a pusher-wire or guide-wire inserted into the lumen of the implant/catheter and either driven by motor or advanced by hand, as appropriate to the implant's location, direction of movement, and targeted point of delivery. Thus comprising a drive unit for imparting rotational motion to the tool (see Col. 12, Lines 1-25). Furthermore, the tool is inherently a cutting tool as it penetrates tissue to deliver drug substance to a desired target location (see Fig. 1). Also inherent in the disclosure of the use of an MR or x-ray imaging device are the method steps of locating the axis of the shaft 2 of the microcatheter 1 and locating the center line of each marker and as well as identifying 3 generally rectangular areas which represent the markers 6, determining the location of a line on each of the rectangular areas and determining the angle between the lines on adjacent ones of the rectangles (all done within or by the processor that comprises pad of the MR or x-ray imaging device). **In regard to claims 6 and 15**, Figure 1 shows that the planes defined by the axially spaced edges of each marker 6 are parallel to one another and perpendicular to the axis of the shaft 2.

Claims 3, 4, 7, 13-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. (U.S. Patent No. 6,272,370) in view of Ben-Haim (U.S. Patent No. 6,203,493).

In regard to claims 3, 4, 7, 13-14 and 16, Gillies et al. teach two markers 6 on the microcatheter 1 (see Figure 1). However, Ben-Haim discloses a similar tracking device for an endoscope comprised of a sheath 20 having a plurality of sensors 22

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spaced along the axis of the endoscope (see Figure 1). Furthermore, duplicating the components of a prior art device is a design consideration within the skill of the art. In *re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the microcatheter 1 with at least three markers 6, in the manner disclosed by Ben-Haim. Furthermore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the microcatheter h of Gillies et al. with a sheath containing the markers 6, in the manner disclosed by Ben-Haim, as Ben-Haim demonstrates that sheaths containing radio-opaque markers for placement over an surgical device are well known in the art.

Response to Arguments

Applicant's arguments with respect to claims 2-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

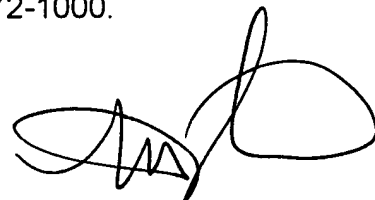
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MJK *MJK*

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SUPERVISORY PATENT EXAMINER
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